

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC., ET AL.,)	
)	
Plaintiffs,)	C.A. No. 08-21-GMS-LPS
)	(Consolidated)
v.)	
)	JURY TRIAL DEMANDED
COBALT LABORATORIES INC., ET AL.,)	
)	
Defendants.)	

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S
ANSWER, DEFENSES AND COUNTERCLAIMS**

Defendants Apotex Inc. and Apotex Corp., for their Answer, Defenses and Counterclaims, to the Complaint of Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH, state and allege as follows:

PARTIES

1. Plaintiff Forest Laboratories, Inc. ("Forest Labs") is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

3. Plaintiff Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

4. Plaintiff Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as “Merz”).

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

5. Upon information and belief, Defendant Apotex Corp. (“Apotex USA”) is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Apotex Inc., having a principal place of business at 2400 N. Commerce Parkway, Weston, Florida, 33326.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit Apotex Corp. is a Delaware corporation with a place of business at 2400 N. Commerce Parkway, Weston, Florida, 33326; otherwise denied.

6. Upon information and belief, Defendant Apotex Inc. (“Apotex”) is a Canadian corporation having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada,

M9L 1T9. Upon information and belief, Defendant Apotex, itself and through its wholly-owned subsidiary and agent Defendant Apotex USA, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit Apotex Inc. is a Canadian corporation with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. It is further admitted Apotex Inc. manufactures generic drug products for sale and use in the United States; otherwise denied.

NATURE OF THE ACTION

7. This is a civil action for infringement of United States Patent No. 5,061,703 (“the ‘703 patent”) (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit Forest Laboratories Inc., *et al.* purport to bring this action under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* for infringement of U.S. Patent No. 5,061,703 (“the ‘703 patent”); otherwise denied.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit this Court has subject matter jurisdiction over the action pursuant to 28 U.S.C. § 1331 and 1338(a).

9. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiff Forest Labs, a Delaware

corporation. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit the Court has personal jurisdiction over Apotex Corp.; otherwise denied.

10. This Court has personal jurisdiction over Defendant Apotex USA by virtue of the fact that, *inter alia*, Apotex USA is a Delaware corporation.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit this Court has personal jurisdiction over Apotex Corp.; otherwise denied.

11. This Court has personal jurisdiction over Defendant Apotex by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Apotex USA; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Apotex USA.

ANSWER: Apotex Inc. and Apotex Corp. deny.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit venue is proper in this judicial district as to Apotex Corp. pursuant to 28 U.S.C. §§ 1391 and 1400(b); otherwise denied.

THE PATENT-IN-SUIT

13. On October 29, 1991, the '703 patent, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Merz has been, and continues to be, the sole assignee of the '703 patent since its issuance.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit on its face the ‘703 patent titled “Adamantane Derivatives In The Prevention And Treatment Of Cerebral Ischemia” indicates it was issued on October 29, 1991 and lists as the assignee “Merz + Co. GmbH & Co.” It is further admitted Reexamination Certificate No. 5,061,703 C1 identifies as the assignee “Merz Pharma GmbH & Co. KGaA, Frankfurt am Main (DE)”; otherwise denied.

14. Forest is the exclusive licensee of the ‘703 patent in the United States. Forest holds New Drug Application (“NDA”) No. 21-487 for Namenda® brand memantine hydrochloride tablets. The ‘703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for Namenda®.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit the ‘703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for Namenda®; otherwise, Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

15. Forest is the exclusive distributor of Namenda® in the United States.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

16. On August 18, 2004, Merz submitted a request to the PTO for reexamination of the ‘703 patent. The PTO issued a reexamination certificate (Exhibit B) for the ‘703 patent on November 7, 2006.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit on its face Ex Parte Reexamination Certificate No. US 5,061,703 C1 indicates it was issued on November 7, 2006 as

a result of Reexamination Request No. 90/007,176, dated Aug. 18, 2004; otherwise Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

ACTS GIVING RISE TO THE ACTION

**Infringement Of The '703 Patent By
Defendants Apotex and Apotex USA**

17. Upon information belief, Defendant Apotex, through its subsidiary and agent Apotex USA, submitted ANDA No. 90-244 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Apotex Generic Products"). ANDA No. 90-244 specifically seeks FDA approval to market the Apotex Generic Products prior to the expiration of the '703 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") No. 90-244 pursuant to 21 U.S.C. § 355(j) seeking approval to market 5mg and 10mg Memantine Hydrochloride Tablets; otherwise denied.

18. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Apotex alleged in ANDA No. 90-244 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Apotex Generic Products. Plaintiffs received written notification of ANDA No. 90-244 and its § 505(j)(2)(A)(vii)(IV) allegation on or about April 23, 2008.

ANSWER: Apotex Inc. and Apotex Corp. admit.

19. Apotex's submission of ANDA No. 90-244 to the FDA, through its subsidiary and agent Apotex USA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement

of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially manufactures, uses, offers to sell, sells, or imports any of the Apotex Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Apotex Inc. and Apotex Corp. deny.

20. Apotex USA is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Apotex USA participated in, contributed to, aided, abetted and/or induced Apotex's submission of ANDA No. 90-244 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: Apotex Inc. and Apotex Corp. deny.

21. Apotex USA's participation in, contribution to, aiding, abetting and/or inducement of the submissions of ANDA No. 90-244 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex USA commercially manufactures, uses, offers to sell, sells, or imports any of the Apotex Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Apotex Inc. and Apotex Corp. deny.

22. Apotex and Apotex USA were aware of the '703 patent prior to filing ANDA No. 90-244.

ANSWER: Apotex Inc. and Apotex Corp. admit.

23. Apotex's and Apotex USA's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: Apotex Inc. and Apotex Corp. deny.

24. Plaintiffs will be irreparably harmed by Apotex's and Apotex USA's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Apotex Inc. and Apotex Corp. deny.

DEFENSES

FIRST DEFENSE: INVALIDITY

The '703 patent is invalid on grounds specified in United States Code, Title 35, including the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

SECOND DEFENSE: NON-INFRINGEMENT

Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid claim of the '703 patent. ANDA application 90-244 does not infringe any valid claim of the '703 patent. The proposed drug products for which approval is sought under ANDA application 90-244 do not directly or indirectly infringe any valid claim of the '703 patent.

COUNTERCLAIMS

Counterclaimants Apotex Inc. and Apotex Corp. for their counterclaims against counter-defendants Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH ("Forest Labs *et al.*") allege as follows:

PARTIES AND JURISDICTION

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. On information and belief, Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

4. On information and belief, Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda.

5. On information and belief, Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

6. On information and belief, Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

7. Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH purport to own the entire right, title and interest of the '703 patent titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia".

8. Forest Laboratories Holdings, Ltd. purports to be the exclusive licensee of the '703 patent in the United States, and purports to hold New Drug Application ("NDA") No. 21-487 for Namenda® brand memantine hydrochloride tablets.

9. Apotex Inc. submitted an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug and Cosmetic Act, naming Apotex Corp. as U.S. agent pursuant the requirements of 21 C.F.R. 314.50(a)(5). Apotex Inc.'s ANDA seeks approval to market Memantine Hydrochloride 5mg and 10mg tablets as defined in ANDA 90-244.

10. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.95, Apotex Inc. certified to Forest Labs *et al.* the '703 patent is invalid and/or will not be infringed by the

manufacture, use, or sale of the proposed products for which ANDA application 90-244 was submitted.

11. Forest Labs *et al.* have commenced this civil action against Apotex Inc. and Apotex Corp. alleging patent infringement.

12. This case arises under the Constitution, laws or treaties of the United States, viz., 35 U.S.C. §§ 1-376, which is an Act of Congress relating to patents, and 21 U.S.C. § 355, which provide subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 271(e)(5).

13. Venue and personal jurisdiction as to Forest Labs *et al.* are proper in this district because Forest Labs *et al.* have availed themselves of the Courts of this jurisdiction in bringing suit against Apotex Inc. and Apotex Corp., thereby submitting themselves to the jurisdiction of this Court.

14. A real, actual and justiciable controversy exists between Apotex Inc. and Apotex Corp. on the one hand and Forest Labs *et al.* on the other hand regarding the invalidity of the '703 patent and Apotex Inc.'s and Apotex Corp.'s non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 (2005).

COUNT I – DECLARATION OF INVALIDITY

15. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 14 as though set forth fully herein.

16. The '703 patent is invalid on grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT II – DECLARATION OF NON-INFRINGEMENT

17. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 16 as though set forth fully herein.

18. Apotex Inc. and Apotex Corp. do not infringe, either directly or indirectly, any valid claim of the '703 patent. ANDA 90-244 does not infringe, either directly or indirectly, any valid claim of the '703 patent. The proposed products for which approval is sought under ANDA 90-244 do not directly or indirectly infringe any valid claim of the '703 patent.

DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgement:

- a. Finding the '703 patent invalid;
- b. Finding the '703 patent is not infringed in any manner by Apotex Inc. and Apotex Corp.;
- c. Finding this is an exceptional case under 35 U.S.C. § 285; and
- d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand a trial by jury on all issues appropriately tried to a jury.

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Dated: June 25, 2008
871323 / 33167

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on June 25, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on June 25, 2008, the attached document was Electronically Mailed to the following person(s):

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